IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO

MERIT LEASING CO., LLC D/B/A GRANDE POINTE HEALTHCARE,)))
Plaintiff,	Case No.
v.)))
Xavier Becerra, in his official capacity as the Secretary of the United States department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and Chiquita Brooks-LaSure, in her official capacity as the Administrator of the Centers for Medicare & Medicaid Services; THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, Defendants.	

COMPLAINT FOR DECLARATORY JUDGMENT AND OTHER RELIEF

Plaintiff Merit Leasing Co., LLC d/b/a Grande Pointe Healthcare ("Grande Pointe"), by and through its attorneys, Benesch, Friedlander, Coplan and Aronoff, LLP, hereby seeks a declaratory judgment stating that the extrapolation process utilized by CMS (defined below) without giving providers meaningful process to challenge its use violates the Constitution's Due Process clause, an injunction prohibiting CMS from using statistical extrapolation

without first providing a meaningful process for providers to challenge the applicability of statistical extrapolation to the case, and other relief, against Defendants Xavier Becerra, in his official capacity as the Secretary of the United States department of Health and Human Services ("HHS"); and Chiquita Brooks-LaSure, in her official capacity as the Administrator of the Department of Health And Human Services Centers for Medicare and Medicaid Services ("CMS") ("HHS" and "CMS are collectively the "Defendants"). In support of this Complaint, Grande Pointe, through counsel, states as follows:

NATURE OF THE CASE

- 1. Grande Pointe is a skilled nursing facility certified to provide services for private-pay patients, patients with private insurance, and patients insured by the Medicare and Medicaid programs. Grande Pointe is part of the CommuniCare Family of Companies, a network of skilling nursing, rehabilitation, and senior healthcare facilities with locations throughout Indiana, Maryland, Missouri, Ohio, Pennsylvania, Virginia, and West Virginia. CommuniCare is one of the nation's largest providers of post-acute care. This action arises out of Defendants' conduct which has deprived Grande Pointe of its constitutional right to due process.
- 2. Specifically, prior to initiating an audit of Grande Pointe,
 Defendants made the purportedly irrevocable decision to use a concept called

statistical "extrapolation," pursuant to which Defendants decided to take the results of an audit of small sample size of Grande Pointe's claims for payment and extrapolate the results over a larger population of patients and claims. In this case, Defendants conducted an audit to see if Grande Pointe submitted sufficient documentation to justify some of its claims for payment to Medicare/Medicaid. The initial audit covered 64 claims for 107 services "randomly selected" from the 2006-2008 billing period. Defendants initial audit determined that the billing error rate and payment error rate were approximately 93 percent and 32 percent, respectively, resulting in an alleged overpayment for those 64 claims of \$127,413.78. Defendants, in an attempt to squeeze blood from a turnip, then extrapolated that result over 1,248 claims for the same time period, resulting in a demand for \$2,119,151.

3. Grande Pointe immediately challenged Defendants' audit finding. Over an almost ten-year odyssey – starting with a 2011 audit and ending with a favorable Administrative Law Judge decision in 2021 – through the snarl of the administrative procedure required when challenging these types of audit findings, Grande Pointe eventually "prevailed" after a trial before an Administrative Law Judge. The Judge overturned 47 out of the remaining 50 of Defendants' claims of error, resulting in a reduction of the alleged payment and billing error rates (in the small sample size of 64 claims) from 93 percent and 32 percent, respectively, to 21 percent and 9 percent. This reduced the

alleged overpayment related to the audited claims from \$127,413.78 to \$37,304.69.

- 4. Despite internal rules stating that certain requirements need to be met to use extrapolation, including a high error rate determination (which is defined as greater than or equal to 50 percent), Defendants persisted in their blind quest to squeeze every nickel from Grande Pointe. They continued to apply extrapolation, resulting in a calculation of \$417,275 in overpayments owed by Grande Pointe instead of \$37,304.69.
- 5. Grande Pointe attempted to request an appeal of Defendants' decision to use extrapolation in the post-ALJ low-error-rate context, but Defendants insisted that its decision was unappealable and unreviewable either administratively or judicially, thus necessitating this lawsuit to determine whether the Defendants' *ex ante* decision to use extrapolation without providing providers a legal process to challenge its use violates Grande Pointe's constitutional due process rights.

THE PARTIES

- 6. Plaintiff Grande Pointe is a skilled nursing facility incorporated in Ohio with its principal place of business in Cuyahoga County, Ohio, located in the Northern District of Ohio, where it has been operating since 2004.
- 7. Defendant Xavier Becerra, named in his official capacity, is the Secretary of the United States Department of Health and Human Services.

- 8. HHS is a federal agency organized under the laws of the United States. It is responsible for administering federal healthcare policy and is the cabinet-level department of which the Centers for Medicare & Medicaid Services is a part.
- 9. Defendant Chiquita Brooks-LaSure, named in her official capacity, is the Administrator of CMS.
- 10. CMS is a federal agency organized under the laws of the United States. CMS is responsible for federally administering the Medicare Program. CMS, either personally or through duly authorized contractors working under CMS's direction, conducted the audit of Grande Pointe in question in this case. CMS also made the ultimate decisions to employ extrapolation in this case and to deny Grande Pointe the ability to administratively appeal CMS's decision to use extrapolation.

JURISDICTION AND VENUE

11. The Constitution vests federal courts with the authority to hear cases "arising under th[e] Constitution [or] the Laws of the United States." U.S. Const. art III, § 2. Congress vests federal district courts with subject-matter jurisdiction over cases involving questions of federal law. "The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Thus, this Court has jurisdiction over this action because all of the claims arise under

the Constitution.

12. Venue is proper pursuant to 28 U.S.C. § 1391(e)(1)(C) because Defendants are officers of the United States, no real property is at issue in this lawsuit, and Grande Pointe is a resident of the Northern District of Ohio.

BACKGROUND FACTS

- I. CMS Performs an Audit of Grande Pointe's Medicare Claims and Notifies Grande Point of Alleged Overpayments
- 13. Grande Pointe provided skilled nursing facility services to multiple beneficiaries in the Northern District of Ohio and elsewhere during the period from January 1, 2006 through December 31, 2008 and received reimbursement from CMS for these services.
- 14. In 2011, a contractor for CMS operating pursuant to Medicare Act, § 102(a), 42 U.S.C.A. § 1395kk(a) and the Health Insurance Portability and Accountability Act of 1996, § 202(a), 42 U.S.C.A. § 1395ddd(f)(3), performed an audit of Grande Pointe's Medicare claims. As part of this audit, the contractor allegedly reviewed a "randomly selected" sample of 64 Grande Pointe's billing claims for 107 nursing and therapy services from 2006 to 2008.
- 15. On or about December 21, 2011, CMS's contractor notified Grande Pointe that CMS had determined that based on its audit of the 107 services: 13 services were allowed as billed, 15 services were denied, and 79 services were downcoded from the billed Resource Utilization Group ("RUG") to a lower

RUG based on the documentation that Grande Pointe supplied as part of the billing process. This resulted in CMS's contractor concluding that CMS overpaid Grande Pointe \$127,413.78 on these 64 claims. This represented a billing and payment error rate in this sample size of approximately 93 percent and 32 percent, respectively. CMS then employed statistical extrapolation across a universe of 1,248 claims for the same time period and demanded that Grande Pointe repay CMS in the amount of \$2,119,151. Grande Pointe paid CMS \$2,119,151 but reserved its right to challenge CMS's audit findings.

II. Grand Pointe Administratively Contests CMS's Overpayment Determinations

- 16. On March 1, 2012, Grande Pointe gave notice of its intent to appeal the overpayment determination with respect to certain errors in calculation of the overpayment amount and to provide additional information.
- 17. On April 5, 2012, Grande Pointe formally appealed CMS's contractor's determination in 83 of the 107 services that were reviewed as part of the audit.
- 18. From May 2012 through October 2013, CMS, again acting through a private contractor, issued various redetermination decisions, some of which were favorable to Grande Pointe and some of which were unfavorable.
- 19. From May 2012 through December 2013, Grande Pointe submitted requests for reconsideration to appeal the contractor's unfavorable decisions.

20. In a February 3, 2015 letter, CMS, through a contractor, issued an unfavorable decision on the appeals discussed above, maintaining that the statistical audit was consistent with the Medicare Program Integrity Manual ("PIM"), extrapolation was validly used, and the amount owed was \$2,119,151.

III. Administrative Law Judge Issues a Partially Favorable Decision and Overturns the Overpayment Errors

- 21. On April 1, 2015, Grande Pointe appealed CMS's decision to an Administrative Law Judge.
- 22. On or about May 6, 2015, CMS, through a contractor, issued a revised decision on the appeals. In the letter, the contractor stated, "[t]he original decision was amended to provide further clarification under the explanation of the decisions."
- 23. On March 15, 2022, Administrative Law Judge Knapp issued a decision in Grande Pointe's favor on 47 of the 50 appealed claims. After the ALJ rendered his decision, the total billing error rate from the sample of 64 claims decreased from approximately 93 percent to 21 percent, and the payment error rate decreased from approximately 32 percent to 9 percent. This changed the overpayment amount from the same from \$127,413.78 to \$37,304.69.
- 24. Grand Pointe stood ready to pay the \$37,304.69 owed, noting that since the billing and payment error rates decreased to approximately 21

percent and 9 percent respectively, the PIM dictates that extrapolation should not be used to expand the alleged overpayment from the sample audited to the entire patient population. Nonetheless, on August 23, 2022, a CMS contractor notified Grande Pointe that the overpayment owed was \$417,275, which represented an extrapolation of the error rate found on the 64-claim sample from 2006-2008 to the entire universe of 1,248 claims for that same time period.

- 25. Between July 27, 2022 and September 16, 2022, Grande Pointe received refund amounts on the difference between the \$2.1 million originally repaid and the revised amount of \$417,275, but CMS continued to withhold the \$417,275 plus interest.
- 26. Upon realizing that CMS seemed intent on using extrapolation, on August 23, 2022, Grande Pointe wrote to the ALJ attempting to challenge CMS's use of extrapolation after the ALJ's prior ruling substantially reduced the alleged error rate.
- 27. On August 31, 2022, the ALJ responded via voicemail message indicating that the ALJ cannot do anything regarding the effectuation of ALJ orders.
- 28. On November 8, 2022, Grande Pointe wrote to CMS contesting their use of extrapolation after the ALJ reduced the error rate to approximately 9 percent and requesting to appeal.

29. On November 18, 2022, CMS responded, tacitly acknowledging that this case did not meet the criteria listed in the Medicare regulations for use of extrapolation. Instead, CMS stated that it was entitled to use extrapolation under its PIM because CMS made the decision to do so "prior to creating a statistical sample and issuing a request for medical records from the provider/supplier." CMS refused to allow Grande Pointe to administratively appeal CMS's *ex ante* decision to use extrapolation.

APPLICABLE LAW

- 30. Before using extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error. 42 U.S.C. § 1395ddd(f)(3); PIM Section 8.4.1.2.
- 31. For purposes of extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to:
 - a. high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review);
 - b. provider/supplier history (i.e., prior history of non-compliance for the same or similar billing issues, or historical pattern of non-compliant billing practices);
 - c. CMS approval provided in connection to a payment

suspension;

- d. information from law enforcement investigations;
- e. allegations of wrongdoing by current or former employees of a provider/supplier; and/or (whistleblower); or,
- f. audits or evaluations conducted by the OIG. PIM Section 8.4.1.4.
- 32. Extrapolation should not be used when the above criteria is not met unless prior approval is given by the Contracting Officer's Representative ("COR") and the Business Function Lead ("BFL"). *Id.*
- 33. Defendants' determinations of "sustained or high levels of payment errors" are not subject to administrative or judicial review." 42 U.S.C. § 1395ddd(f)(3). See Gentiva Healthcare Corp. v. Sebelius, 723 F.3d 292, 297 (D.C. Cir. 2013); Palm Valley Healthcare, Inc. v. Azar, 947 F.3d 321, 329 (5th Cir. 2020).

COUNT I

<u>Constitutional Violation (Due Process Violation – Failure to Provide Process to Challenge CMS's Erroneous Use of Extrapolation) – Declaratory Judgment</u>

- 34. Grande Pointe reasserts and incorporates by reference all allegations contained in Paragraphs 1 through 33 above.
- 35. Grande Pointe has a clear and ascertainable right in need of protection. Under the 14th Amendment of the United States Constitution, no state shall "deprive any person of life, liberty, or property, without due process

of law; nor deny to any person within its jurisdiction the equal protection of the laws." U.S. Const., amend. XIV, § 1.

- 36. Grande Pointe has a property interest in the money it has received or should receive from CMS in exchange for Grande Pointe providing patient care. CMS has deprived Grande Pointe of a minimum of \$379,971 through its erroneous decision to use extrapolation in this case.
- 37. The lack of administrative or judicial review of CMS's decision to use extrapolation in this case violates the Constitution's Due Process Clause.

WHEREFORE, Grande Pointe respectfully requests that this Court:

- A. Declare that Defendants have violated Grande Pointe's due process rights by failing to give Grande Pointe a procedure to challenge Defendants' decision to use extrapolation after the ALJ determined that Grande Pointe had less than a 10 percent error rate;
- B. Enjoin Defendants from using extrapolation in this case and otherwise enjoin Defendants from withholding payment from Grande Pointe based on Defendants' statistical extrapolation unless and until a Constitutionally sufficient procedure is put in place under which Grande Pointe may challenge CMS's decision to use extrapolation;
- C. Order Defendants to return any money already withheld from Grande Pointe based on their extrapolation analysis; and
 - D. Award Grande Pointe such other and further relief as this Court

deems just and proper, including an award of Grande Pointe's attorneys' fees and costs.

COUNT II

Constitutional Violation (Due Process Challenge to Defendants' Ex Ante Decision to Use Extrapolation) – Declaratory Judgment

- 38. Grande Pointe reasserts and incorporates by reference all allegations contained in Paragraphs 1-37 above.
- 39. In its most recent correspondence, dated November 18, 2022, Defendants justified their continued use of extrapolation not based upon a sustained high error rate or any other criteria prescribed by statute. Instead, they justified it because they claim to have decided to use extrapolation prior to conducting the audit of Grande Pointe.
- 40. Specifically, Defendants referenced the following provision of the Medicare Program Integrity Manual:

If the contractor believes that statistical sampling and/or extrapolation should be used for purposes of estimation, and it does not meet any of the criteria listed above [sustained high error rate], it shall consult with its COR and BFL prior to creating a statistical sample and issuing a request for medical records from the provider/supplier. Examples of this may include, but are not limited to: billing for non-covered services, billing for services not rendered, etc. Extrapolation should not be used when the above criteria is not met unless prior approval is given by the COR and BFL.

41. This directly conflicts with the actual law, which specifically states that before using extrapolation to determine overpayment amounts to be

recovered by recoupment, offset, or otherwise, there must be a determination of sustained or high level of payment error . . . 42 U.S.C. § 1395ddd(f)(3).

42. Defendants' decision to use extrapolation *ex ante* – without first determining if there is any error – without giving a provider the opportunity to contest the use of extrapolation through administrative or judicial process violates the Constitution's Due Process Clause.

WHEREFORE, Grande Pointe respectfully requests that this Court:

- A. Declare that Defendants have violated 42 U.S.C. § 1395ddd(f)(3).
- B. Declare that Defendants violated Grande Pointe's due process rights by failing to give Grande Pointe a procedure to challenge Defendants' *ex* ante decision to use extrapolation after the ALJ determined that Grande Pointe had less than a 10 percent error rate;
- C. Enjoin Defendants from using extrapolation in this case and otherwise enjoin Defendants from withholding payment from Grande Pointe based on Defendants' statistical extrapolation unless and until a Constitutionally sufficient procedure is put in place under which Grande Pointe may challenge CMS's decision to use extrapolation;
- D. Order Defendants to return any money already withheld from Grande Pointe based on their extrapolation analysis; and,
- E. Award Grande Pointe such other and further relief as this Court deems just and proper, including an award of Grande Pointe's attorneys' fees

and costs.

COUNT III

Constitutional Violation (Constitutional Due Process Challenge to 42 U.S.C. § 1395ddd(f)(3)) – Declaratory Judgment

- 43. Grande Pointe reasserts and incorporates by reference all allegations contained in Paragraphs 1-42 above.
- 44. To the extent that Defendants may assert that they have the right to use extrapolation because they claim that Grande Point has a sustained high error rate, 42 U.S.C. § 1395ddd(f)(3) prevents administrative or judicial review of Defendants' decision.
- 45. Congress cannot legislate around the Due Process Clause. 42 U.S.C. § 1395ddd(f)(3) is unconstitutional because it violates the Due Process Clause.

WHEREFORE, Grande Pointe respectfully requests that this Court:

- A. Declare 42 U.S.C. § 1395ddd(f)(3) unconstitutional. Further declare that Defendants have violated Grande Pointe's due process rights by failing to give Grande Pointe a procedure to challenge Defendants' decision to use extrapolation;
- B. Enjoin Defendants from using extrapolation in this case and otherwise enjoin Defendants from withholding payment from Grande Pointe based on Defendants' statistical extrapolation unless and until a Constitutionally sufficient procedure is put in place under which Grande

Pointe may challenge CMS's decision to use extrapolation;

- C. Order Defendants to return any money already withheld from Grande Pointe based on their extrapolation analysis; and
- D. Award Grande Pointe such other and further relief as this Court deems just and proper, including an award of Grande Pointe's attorneys' fees and costs.

Dated: April 24, 2023.

Respectfully Submitted,

BENESCH, FRIEDLANDER, COPLAN & ARONOFF LLP

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